

P A T E N T

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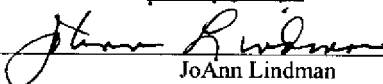
Application No.: 10/595,977 Confirmation No.: 1136
Applicant : Mark Ashby et al.
Filed : June 14, 2007
TC/A.U. : 3773
Examiner : Mark F. Mashack
Title : HEMOSTATIC PRESSURE PLUG
Docket No. : 1001.2219102
Customer No. : 28075

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
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CERTIFICATE FOR ELECTRONIC TRANSMISSION: The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 10 day of December, 2008.

By _____


JoAnn Lindman

Dear Sir:

Appellant respectfully requests a Pre-Appeal Brief Review of the pending application. A Notice of Appeal is filed herewith.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

Appellants have carefully reviewed the Final Office Action of October 17, 2008. Currently claims 1, 27, 40-49, 59, and 60 are pending in the application and have been rejected by the Examiner. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 1, 40-42, and 59-60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,700,277), hereinafter Nash, in view of Hannam et al. (U.S. Patent No. 5,649,959), hereinafter Hannam. After careful review, Applicant must respectfully traverse this rejection. Applicants respectfully traverse the rejection for at least the reasons that all elements of these claims are not disclosed in this combination of references and that the combination proposed by the Examiner would impermissibly alter the principle of operation of both Nash or Hannam or would render Nash or Hannam unsuitable for their intended purpose. As such, the pending claims are believed to be allowable over these references.

The instant invention, as described in independent claims 1 and 40, provides a flexible plug or flexible disk which may be positioned within a blood vessel where it circumferentially covers and seals a blood vessel puncture site from within the vessel. The flexible plug or flexible disk is maintained in position by differential pressure between the interior of the vessel and the pressure adjacent to the vessel. In claim 1, the plug is explicitly released intravascularly at the blood vessel puncture site.

Nash and Hannam both disclose closure devices which employ an external seal held in place in the tract adjacent to the vessel by an intravascular anchor in cooperation with a tensioned filament connecting the anchor to the external seal material. Nash employs a locking means which permanently prevents said sealing means from moving away from said anchoring means thus clearly indicating that the sealing means is separate and distinct from the anchoring means. (See claim 1 of Nash.) Nash teaches pulling the sealing means into the external tract by means of a filament and a pulley-like arrangement. The Examiner has stated that Nash is silent on the flexibility of the disk, however Nash does not disclose a disk and the intraarterial anchor of Nash is characterized as: "The strip is sufficiently rigid such that once it is in position within the artery or other vessel, duct, or lumen, it is resistant to deformation to preclude it from bending to pass back through the puncture through which it was first introduced." As depicted by Nash in Figs. 1, 2, 3, 4, 5, 6, 7, 8, 9, and 19, the strip is sufficiently narrow to fit through the puncture in the vessel wall and so cannot circumferentially cover the puncture and it is said to seal only in the temporary sense of partially covering the

opening until the external tract seal is in place. The strip of Nash resembles a toggle bolt in form and function.

Further, the Examiner has characterized the action of “severing the proximal end of suture 34” as providing the structural element of a “release mechanism” found in claim 1. The severing of the suture of Nash proximal of the plug and the locking member 36 does not “release” the anchor of Nash. Were it to release the anchor, the anchor of Nash would be free to migrate with potentially lethal effect because nothing other than the suture embedded in the external plug 30 holds it in position. Neither Nash nor Hannam discloses a release mechanism which releases the plug or disk intravascularly. In the pending invention, the pressure differential maintains the disk in position once it is released.

Hannam, cited for the purpose of providing a flexible disk, teaches “The anchor component or member may comprise a relatively thin, narrow strip of material” and further characterizes the strip as “sufficiently rigid such that once it is in position within the artery it is resistant to deformation”. The disk of the invention is sufficiently flexible that it may be folded within the sheath or introducer to pass through the puncture (Fig. 4A), whereas the strips of Nash and Hannam must be rotated 90 degrees and have their long axis aligned with the sheath to be accommodated therein. In the passage found at col. 11, lines 16-20, Hannam clearly indicates that tension is required to maintain the anchor in position: “Next, a tensioning member such as a leaf or similar spring member 62 may be used to apply a steady pressure to the filament member 36 to retain the anchor member 30 in the desired position adjacent to the wall of the artery 24.” Thereupon, a gelatinous material is injected into the incision around a filament to seal the incision from the flow of fluids through the blood vessel. “As the gelatinous material 52 cures and forms a clot in the incision, the gelatinous material 52 frictionally engages the filament member 36 to ensure that the anchor member 30 is retained along the wall of the blood vessel.” Accordingly, the seal of Hannam is formed external to the blood vessel and the anchor is retained in place within the vessel by tension maintained upon the filament by frictional forces between the filament and the gelatinous external seal.

Neither Nash nor Hannam teach an anchor within the vessel which covers the blood vessel puncture site and seals it, wherein the anchor is maintained in position by

differential pressure and both Nash and Hannam teach the tract adjacent to the opening in the vessel with a material either pulled into the tract or formed in situ within the tract by injection after the anchor is positioned and secured by tensioning an attached filament, said material primarily sealing the tract rather than the puncture in the vessel wall. Nash teaches the use of a spacer washer between the anchor and the plug “thereby holding the plug member 30 further away from the opening 24B in the artery 22 than the embodiment of FIGS. 1-3, thereby further ensuring that no portion of the plug will enter the artery.” (See col. 9, lines 27-31.) Neither Nash nor Hannam teach an intravascular seal and both Nash and Hannam appear to allow the vessel to leak through the wall puncture with the blood stopped only within the tract which still allows the formation of a hematoma below the skin.

Further the device of Nash requires a locking member not found in the instant invention. (*Omission of an Element with Retention of the Element's Function Is an Indicia of Unobviousness*. MPEP 2144.04, II., B.) Similarly, the external seal of Nash has been omitted entirely from pending claim 1 and is found in claim 40 only as an integral secondary adjunct to the primary pressure sealing disk rather than as a separate element. Even when an adjunct hemostatic element is coupled to the sealing disk and extends through or lies adjacent to the vessel wall, the resulting apparatus cooperatively seals the puncture in the vessel wall rather than merely blocking the tract adjacent to the puncture.

Accordingly, neither Nash nor Hannam teach a flexible disk or a flexible plug, said disk or plug being sized to circumferentially cover and seal the blood vessel puncture. Instead, they both teach a rigid narrow strip which serves to anchor an external seal in position in the tract adjacent to the blood vessel puncture without sealing the puncture and Nash teaches away from doing so by suggesting that it is desirable to introduce a spacer to avoid allowing any part of the plug to enter the artery. Fig. 4-6 of Nash, cited by the Examiner to show that the strip can cover the puncture, are side views which show the length of the strip and not the width. Were either Nash or Hannam to be modified to cover and to seal the blood vessel puncture and to do so with an intravascular flexible disk or plug, said disk or plug being maintained in position without requiring a tensioned tether, the modification would impermissibly change the principle of operation

of the references. Accordingly, the rejections of independent claims 1 and 40 should be withdrawn.

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (MPEP 2143.01, VI.)

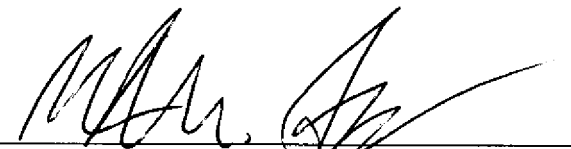
Further claims 27, 41-49, 59, and 60, which depend from independent claims 1 and 40 respectively and add further limitations thereto, are believed to be unobvious over Nash in view of Hannam and Appellants respectfully request that those rejections be withdrawn as well.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: 12/10/08


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